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(71) Applicant
Intelligent Decision Systems S.A.

(Incorporated in Spain)

Paseo de la Castellana 93, 28046 Madrid, Spain

(72) Inventors
Jose Miguel Garcia Santesmases
Javier Martin Rodrigo

(74) Agent and/or Address for Service
E N Lewis & Taylor
5 The Quadrant, Coventry, CV1 2EL, United Kingdom

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(54) Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies

(57) An installation for assisting the diagnosis of cardiovascular and pulmonary pathologies in a patient comprises:
a) a system of collecting information obtained from the user, from a user board containing data peculiar to the patient and from previous experience;
b) a number of non-invasive sensors which will be applied to the patient, such as:
- an air flow meter,
- exhaled gases analyser,
- transcutaneous arterial gases meter,
- etc.;
c) an artifical intelligence system (expert system) making it possible to analyse all the information received in an integrated manner, in order to establish a diagnosis or a diagnostic approximation; and
d) means of storage of the relevant information.

Fig.1

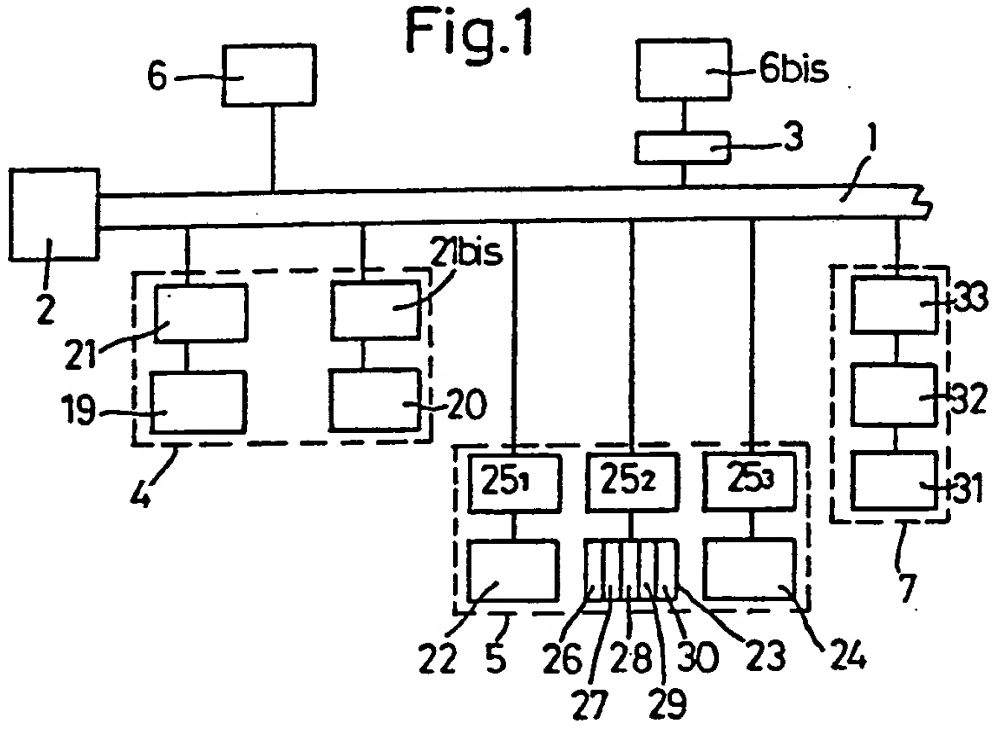

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Fig.1

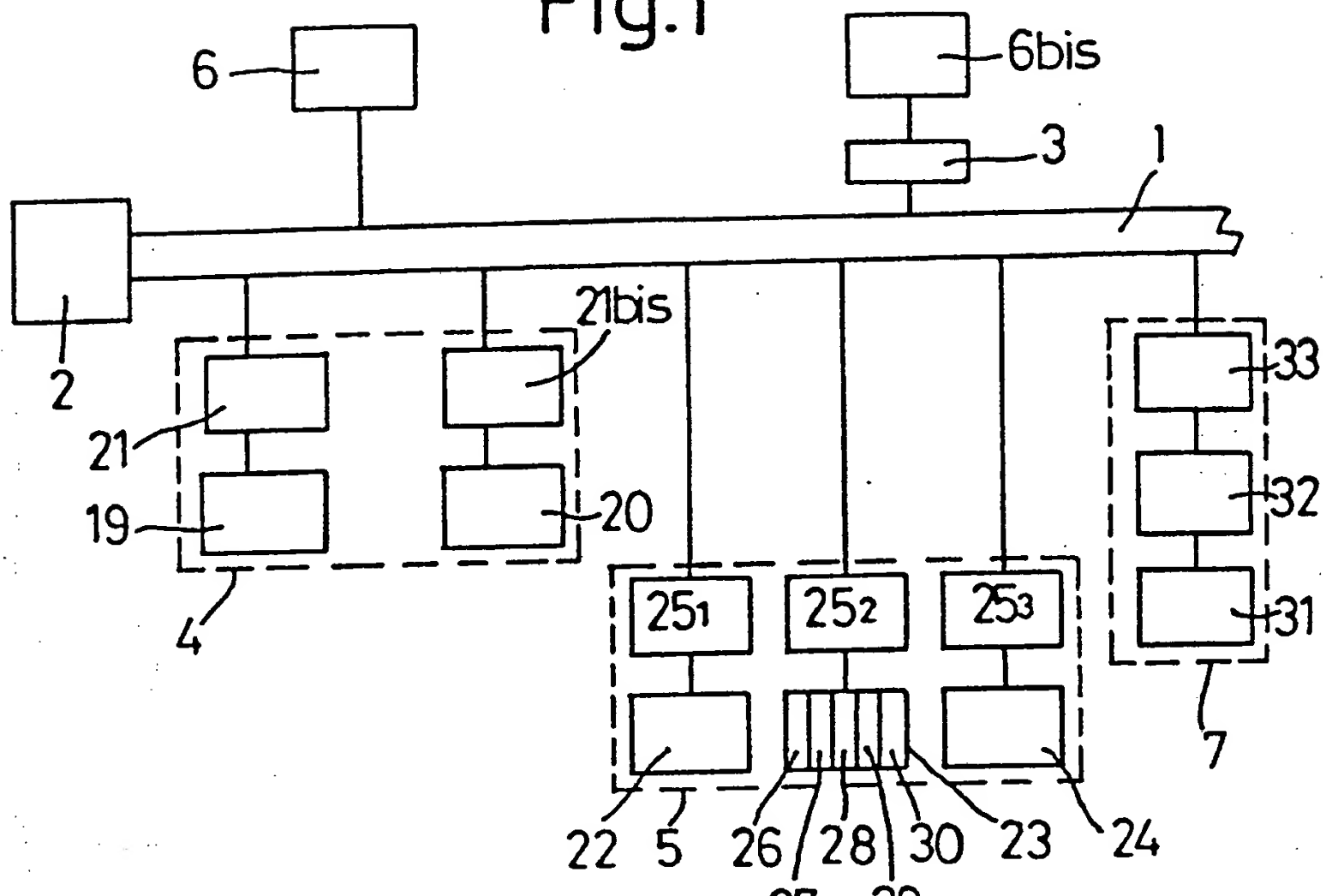

Fig.2

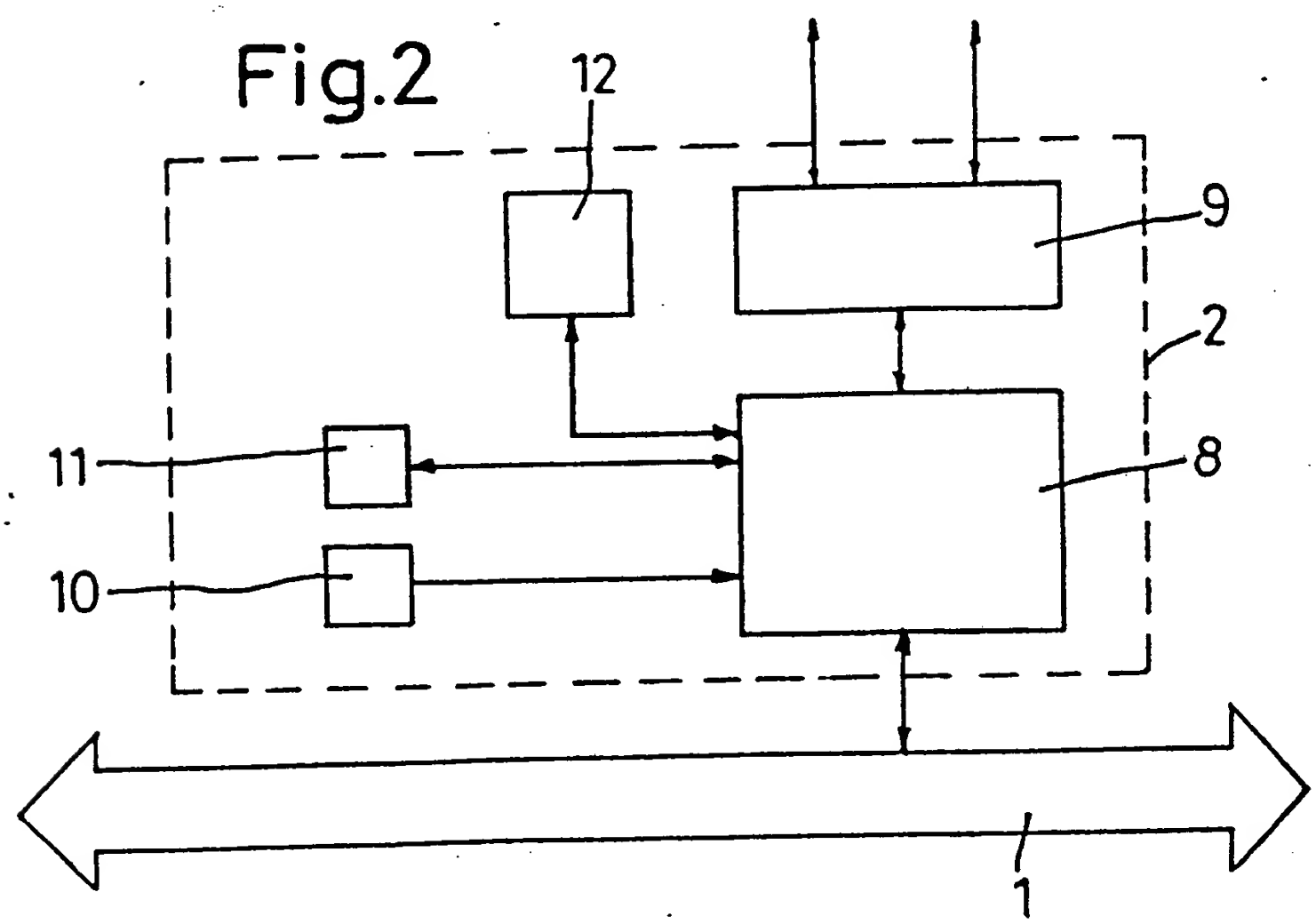

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Fig.3

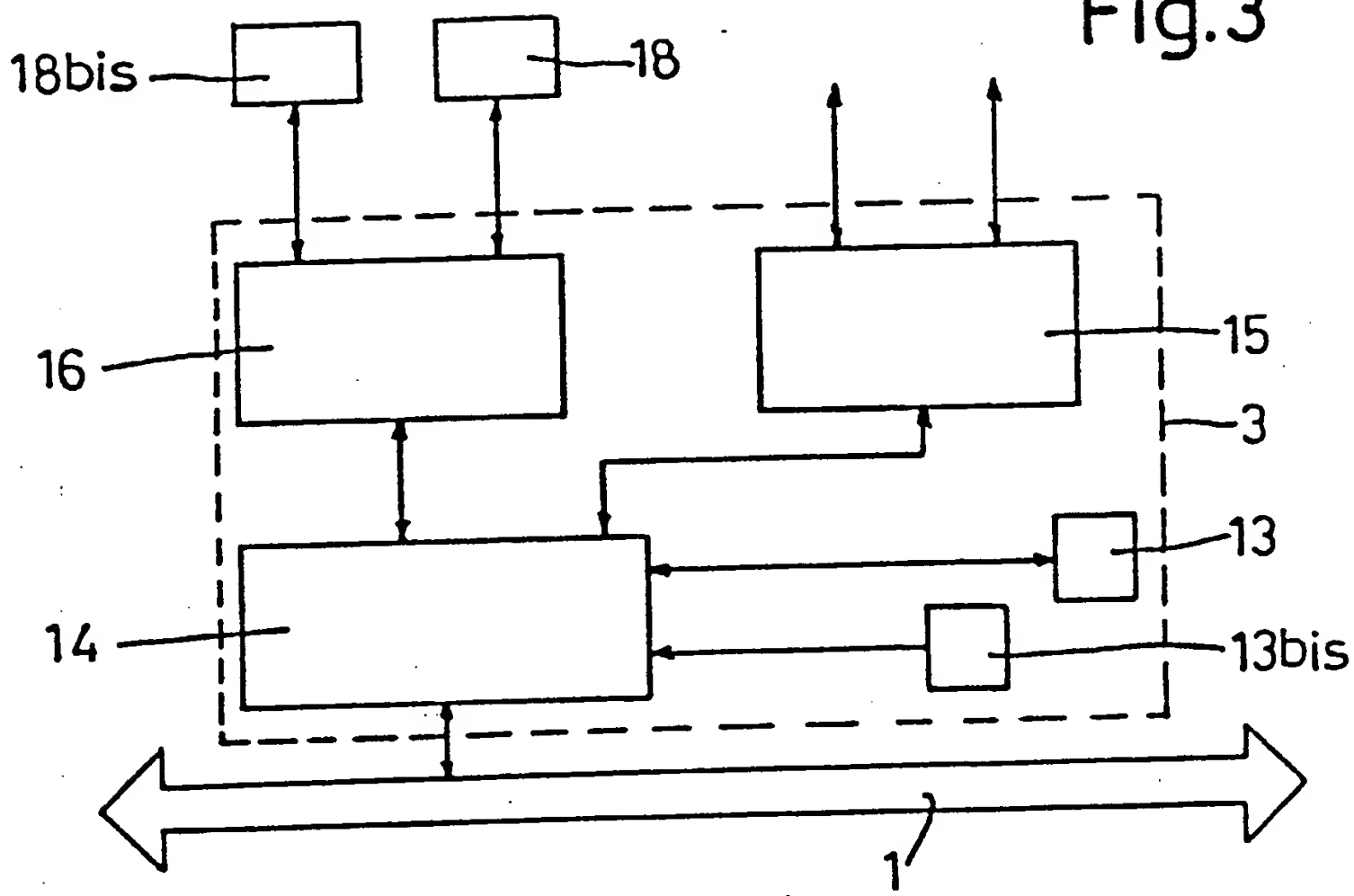
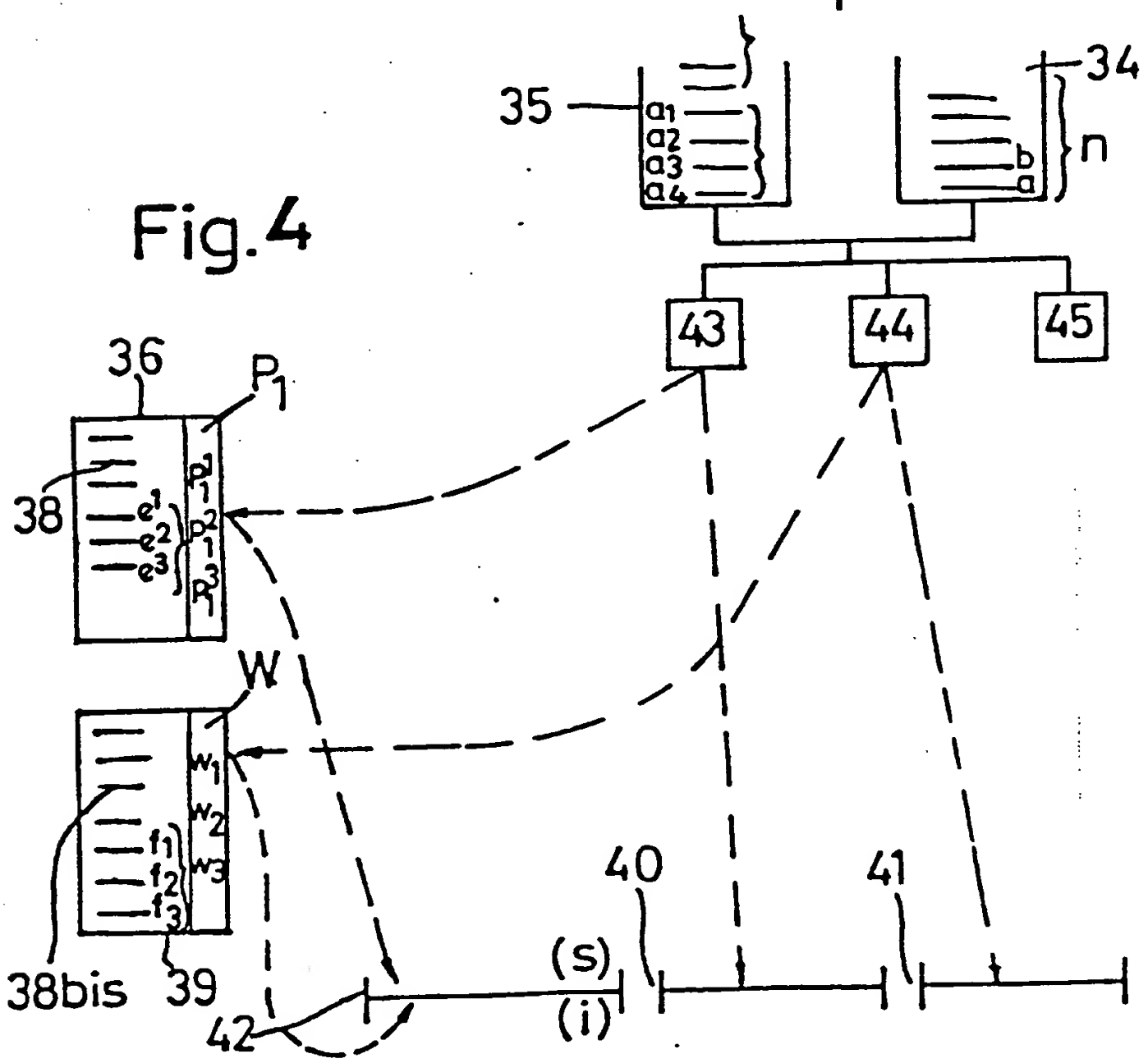


Fig.4



Title: Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies

The present invention relates to the diagnosis of cardiovascular and pulmonary pathologies.

There is at the present time a widespread international consensus that the industrialised countries should try to develop new advanced technological applications in the health field, especially those which can help solve the problems of primary attention, the main vehicle of population health care according to the definition of the 1978 Alma-Ata Conference.

Furthermore, the World Health Organisation, in its programme of "Health for all in the year 2000", also includes the concept of "technology appropriate for health" as one of the most important objectives to be achieved in the near future.

The present invention provides installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, in the form of a modular system ocmprising:

a) a bus relating to the following elements:

b) a main CPU board,

c) a dynamic memory block,

d) a mass memory,

e) en external communications block,

f) a user board block which contains the data peculiar to the user; and an expert system consisting of:

g) a cardiovascular and pulmonary environment knowledge base created from:

g_1) weighted heuristic associations of combined manifestations and diseases,

g_2) weighted objective associations of cardiorespiratory parameters,

g_3) a data base-bank of cardiovascular manifestations, parameters and diseases, the said base being represented in rules and tables of association,

h) an inference motor which manages the knowledge base and the modular system input data, suiting its inference to the medical act.

An installation according to the invention represents a valid diagnostic instrument to be added to the necessary basic technologies so that primary health attention may achieve its objectives, since it offers enormous possibilities in the automatic diagnosis of pulmonary and cardiovascular diseases.

We can in fact easily imagine that, in the 1992 scenario, the installation will be used to improve the diagnostic capability of the Health Centres, which will be used to dispense medical care and preventative services to the citizens of many of the developed countries. Indeed,

already today, many European countries are reorganising their health systems in line with these new concepts, and hundreds of health centres are already in operation throughout Europe.

Other applications for it in the health field will be the specialist practices (cardiological and pneumological) in secondary care and, at tertiary level, the hospitals themselves, in extrenal consultations, pre-operating studies, pulmonary function laboratories, etc.

In the field of preventative medicine an installation according to the invention is of value for studying collective groups, such as students, military personnel, etc., since it can be used to make adequate assessments of the pulmonary and cardiac functions.

However, in this field, the most recent epidemiological investigations are asking for special attention to be given to groups of individuals susceptible to the development of particular diseases, and who are known as risk groups.

In pulmonary medicine, such an installation can be used to detect individuals who, living in polluted environments, or being smokers, are still at the early stages of pulmonary diseases, when the pathological changes are

limited to the small tract and the disease is potentially reversible.

In cardiology, the system is used for the detection of people who have a substantially increased risk of developing coronary disease, through possessing a set of risk factors which are analysed by the installation, allowing the establishment of a coronary risk prognosis index recommended by various researchers and even by certain international organisations.

With regard to sports medicine and from the cardio-respiratory viewpoint, it is almost impossible to imagine a system which can so easily provide a complete set of physiological data which are extremely important for individuals who are going to be subjected to situations of extreme physical stress.

In industrial medicine, such an installation could substantially improve the diagnostic possibilities at the early stages of industrial diseases, basically because of its capacity to detect changes in the pulmonary diffusion capacity and to calculate the volume of lung tissue. It also evaluates the safety of the pathological changes and their careful follow-up. An installation according to the invention assists the diagnosis used for the assessment of certain cardiac and pulmonary pathologies, the physiological

study of the respiratory and cardiovascular systems, and the differential diagnosis with other cardiopulmonary bodies, which involve cardio-respiratory signs or symptoms.

A preferred form of installation according to the present invention consists of various component parts:

a) a system of gathering information obtained from the user and the user board;

b) various non-invasive sensors adapted to the system and which will be applied to the user:

- air flow meter
- exhaled gases analyser
- transcutaneous arterial gases meter
- blood pressure sensor
- electrocardiograph
- effort test
- other options

c) a system of artificial intelligence (expert system), making it possible to analyse in an integrated manner all the information received, in order to establish a diagnosis or a diagnostic approximation;

d) means of storage of the relevant information.

Preferably the external communications block consists of:

a) a printer,

b) a series of non-invasive sensors,

c) other external systems,

all communicating with the bus of the installation through the corresponding interface.

Advantageously, the non-invasive sensors applied to the user to study his physiological situation, are:

a) an air flow meter,

b) an exhaled gases analyser,

c) transcutaneous arterial gases meter,

d) blood pressure sensor,

e) an electrocardiograph,

f) effort test,

having means of supplying digital signals to the installation capable of being understood by it.

Preferably, the expert system consisting of:

a) a questionnaire consisting of questions on the manifestations,

b) a table of specifications of the different possibilities of a manifestation in clause (a),

c) a table with weightings of the diseases which are suggested by a manifestation specified in accordance with clauses (a) and (b),

d) a table with weightings of the diseases habitually showing a manifestation specified in accordance with clauses (a) and (b).

In one embodiment the expert system consists of:

a) a cumulative table of the manifestations present, in which are accumulated the affirmative answers to clause (b) in the above paragraph,

b) a cumulative table of the manifestations absent, in which are accumulated the negative answers to clause (b) in the above paragraph,

c) a cumulative table with combined weighting in which are accumulated positively and in a weighted manner the diseases appearing in clause (c) in the previous paragraph, and negatively in a weighted manner the diseases appearing in clause (d) in the previous paragraph.

The weighting of each disease appearing in the cumulative table may be a weight correlated with the accumulation of weights with which the said disease appears.

A disease is definitively eliminated if the weight appearing in the cumulative weighting table exceeds a predetermined threshold.

The expert system may have means to ensure that the installation acts indiscriminately under the isolated or combined action of the following input data:

a) knowledge base,

b) user board block,

c) block of external communicationn with the non-

invasive sensors.

Preferably, the modular system consisting of an input/ output block which comprises:

a) a screen,

b) a keyboard, both connected to the bus of the installation by one controller for each.

The bus includes the main CPU board, a memory extension board containing the dynamic memory block and a controller board connecting the mass memory to the bus.

The main CPU board may consist of a CPU and various auxiliary circuits for connection to:

a) an interface for series communications,

b) a ROM memory,

c) a static RAM memory,

d) a clock

Conveniently the controller board is provided with an auxiliary CPU and its own memory facilities and the user board block consists of:

a) a board containing the data peculiar to the user, which sends its data to:

b) a board reader, which communicates its information to the bus by means of

c) a controller.

Advantageously it consists of means for asking the installation to supply the situation of the cumulative tables at a given moment, the probable diagnosis being the state of the weighted cumulative table.

The present invention is further described hereinafter, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a block diagram of the installation according to the invention.

Figure 2 is a block diagram of the main CPU board.

Figure 3 is a block diagram of the mass memory access board.

Figure 4 is a functional diagram of the intelligence of the system.

A non-restrictive example of practical execution of this invention is described below. No other methods of execution are described, in which accessory changes are made without altering the basis of the invention; the invention, nevertheless, also covers all its variants.

The installation covered by the invention will basically

consist of a modular bus system, based on a high speed microprocessor, and with a memory management, floating point processor and masking functions included, in addition to auxiliary, built on the basis of semi-custom technologies (PLD's, GATE ARRAYS, STANDARD CELLS).

The most powerful microcontrollers (disk, communications, graphics, etc.) available at the time will be used. The aim is to obtain a minimum design in number of components and space, with the maximum functional and speed performance.

The basic configuration of this installation consists of a modular system based on a VME bus (1) in which will be included a board for the CPU (2) proper with a series communication channels, a memory extension board (6) and a mass memory access controller board (3), an input/output block (4), an external communications block (5), a user board block (7) and a mass memory (6bis).

The provision of a modular system will provide great advantages when the time comes to develop each board, and in the case of the design of future extensions.

The CPU board consists of various blocks:

- CPU + auxiliary circuits (8),
- Interface for series communications (9),
- RAM memory (10)

- Static RAM memory (11),
- Clock (12)

The working frequency of the CPU will preferably be between 12.5 MHz and 20 MHz.

As auxiliary circuits of the CPU (8), a block for "power up-down" is provided, and a date/time actuation clock.

The communication block (9) consists of two RS-232-C series communication channels to allow communication with the rest of the components.

All the necessary routines for carrying out diagnoses, self-testing and system start-up are included in the RAM memory (11).

The CPU board memory consists of a static memory, possibly with the use of "surface mounted devices" to allow a considerable reduction in the space occupied on the board.

The memory extension board (6) consists of a dynamic memory block and a set of circuits for management of the refreshment generation and parity check, and signal detection/generation for the VME bus (1).

The mass memory access board (3) has the job of managing

access to the mass memory (6bis) (hard disk (18) and flexible disks (18bis)). It consists of three basic blocks:

- Buffer memory (13),
- Local microprocessor and auxiliary circuits (14),
- Intelligent controller (16) for the disk units (18) (18bis).

The buffer memory (13) preferably has a capacity of 1 Mbyte of RAM memory and complementary memories (13bis).

The microprocessor (14) manages the intermediate data storage in the buffer (13) and requests for access to the VME bus (1).

Communication with the outside is made through a communication block (15) consisting of two RS-232-C series communication channels.

Each board communicates with the rest of the system via a standard VME bus (1) through which information is exchanged among the different boards and blocks of the installation.

The input/output block (4) contains the man-installation communication elements - usually doctor-installation-, two components of the said block having been shown in Figure 1, namely a screen (19) with the most suitable data presentation, processing and introduction techniques, and a

keyboard (20), both communicating with the installation through controllers (21) (21bis), one for each.

The use of any conventional technique such as light pen, mouse, etc. is assumed.

For the external communications block (5), a printer (22) is provided for handling data of the periodic register, incident register type and to cover the normal requirements; plus a series of non-invasive sensors (23) and other external systems (24), all of them in communication with the installation through the corresponding interfaces (25_1), (25_2), (25_3), working in conjunction or individually.

The non-invasive sensors (23) which are applied to the user to study his physiological situation can be: an air flow meter (26), exhaled gases analyser (27), transcutaneous arterial gases meter (28), blood pressure sensor (29), electrocardiograph (30) and others.

The non-invasive sensors (23) have internal means of supplying the installation with digital signals capable of being understood by it.

The user board block (7) consists of a board (31) containing data peculiar to the user concerning his clinical history, identification and administrative data, etc., a board

reader (32) which can incorporate its own memory and a controller (33) for connection to the installation.

The installation with its expert system works with the information contained in a data base whose sources of knowledge are:

a) knowledge provided by specialists of the ad-hoc medical group in the cardiovascular and respiratory fields, namely:

- heuristic knowledge of an associative nature which relates manifestations with diseases, manifestations with each other and diseases with each other;

- objective knowledge based fundamentally on experimental and physiological models, already tested, of the combined behaviour of particular cardiorespiratory parameters;

b) knowledge acquired by means of a data base-bank.

The associations mentioned in the above paragraphs are made in a weighted manner.

The manifestations can be: manifestations which suggest a disease, manifestations which habitually accompany a disease. Thus, the knowledge base is the result of integrating the

knowledge acquired by both sources.

It is represented in two ways: rules and tables of association.

Both representations satisfy the conditions required from an expert system: the capacity to be extended and to be modified without altering the other elements in it.

The rules and weighted association tables are introduced together with the corresponding auxiliary program into the relevant memory units of the installation.

The following are prepared: a questionnaire (34) with a discrete number of questions (4) which have to be put to the user and which concern manifestations in respect of symptoms, location etc.; a table of specifications (35) in which the different possibilities (9_1), (9_2), (9_3), (9_4) of a particular question (a) about a manifestation in the previous questionnaire (34) are specified; a table (36) with weightings (p_i) of diseases (38) which are suggested by a manifestation determined both from the questionnaire (34) and specified in the table (35); a table (39) with weightings (W) of diseases (38bis) which habitually present a given manifestation; a cumulative table (41) of manifestations absent; a combined cumulative weighting table (42) of probability of the existence of one or more diseases or

of probable diagnosis.

Let us suppose, for example, that the question (a) in the questionnaire (34) is: Where is the pain located ?

The table of specifications (35) offers the following probabilities for this question:

Back - a_1

Side - a_2

Finger - a_3

Diffused - a_4

The user has to answer each of these specifications: confirming (43) or denying (44), or not knowing (45). Let us suppose that he confirms the question specified (a_1), i.e.: pain - back, and that he denies the others (9_2), (9_3), (9_4).

Upon confirming that he has (a_1), there appear in the suggested diseases table (36), the diseases (e^1) (e^2) (e^3) associated with (a_1) with their respective weightings ($P_1{}^1$) ($P_1{}^2$) ($P_1{}^3$), which are sent to table (42) in the positive zone (in this case the upper (a)).

Upon denying that he has the other manifestations (9_2), (9_3), (9_4), there appear in the table (39) of diseases which habitually present each manifestation, and for each of them, the diseases (f^1) (f^2) (f^3) associated, for example, with manifestation (a_2), with their respective weightings (w1),

(w2), (w3), which are sent to table (42) in the negative zone (in this case the lower (i)).

When going through the questionnaire (34) and specifications (35), the same disease can be involved in the probable diagnosis table (42) on various occasions, some in a positive form and others in a negative form. Preferentially and in respect of the appearance for a disease of a positive sequence of forms with their respective weightings. The said disease is given a weigting related to the accumulation of the said weightings. The same thing is done with the negative ones, the probable diagnosis of a disease being definitively eliminated if the weighting related to a pre-determined threshold is exceeded.

The affirmative manifestations (a_1) accumulate in the table (40) of manifestations present, while the negative manifestations (9_2), (9_3), (9_4) accumulate in the table (41) of manifestations absent.

The installation can be asked at any time to indicate the present status of the cumulative tables (40), (41), (42), so that is is possible to know the symptoms which argue positively and negatively for the diagnosis of a disease.

At any moment, and of course at the end, in the weighted accumulation or combined-cumulative weighting table (42),

a series of diseases appear with one positive weighting value and another negative one, which constitute the probable diagnosis.

CLAIMS:

1. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, in the form of a modular system comprising:

a) a bus relating to the following elements:

b) a main CPU board,

c) a dynamic memory block,

d) a mass memory,

e) an external communications block,

f) a user board block which contains the data peculiar to the user; and an expert system consisting of:

g) a cardiovascular and pulmonary environment knowledge base created from:

g_1) weighted heuristic associations of combined manifestations and diseases,

g_2) weighted objective associations of cardiorespiratory parameters,

g_3) a data base-bank of cardiovascular manifestations, parameters and diseases, the said base being represented in rules and tables of association,

h) an inference motor which manages the knowledge base and the modular system input data, suiting its inference to the medical act.

2. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to claim 1, wherein the external communications block consists of:

a) a printer,

b) a series of non -invasive sensors,

c) other external systems,

all communicating with the bus of the installation through the corresponding interface.

3. Installation for assisting the diagnosis of cardio-vascular and pulmonary pathologies, according to claim 2, wherein the non-invasive sensors are applied to the user to study his physiological situation, and comprise one or more sensors selected from the group comprising:

a) an air flow meter

b) an exhaled gases analyser,

c) transcutaneous arterial gases meter,

d) blood pressure sensor,

e) an electrocardiograph,

f) effort test,

having means of supplying digital signals to the installation which are capable of being understood by it.

4. Installation for assisting the diagnosis of cardio-vascular and pulmonary pathologies, according to any preceding claim wherein the expert system consists of:

a) a questionnaire containing questions on the manifestations,

b) a table of specifications of the different possibilities

of a manifestation in clause (a),

c) a table with weightings of the diseases which are suggested by a manifestation specified in accordance with clauses (a) and (b),

d) a table with weightings of the diseases habitually showing a manifestation specified in accordance with clauses (a) and (b).

5. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to claim 4, wherein the expert system consists of:

a) a cumulative table of the manifestations present, in which are accumulated the affirmative answers to clause (b) in claim 4,

b) a cumulative table of the manifestations absent, in which are accumulated the negative answers to clause (b) in claim 4,

c) a cumulative table with combined weighting in which are accumulated positively and in a weighted manner the diseases appearing in clause (c) in claim 4, and negatively in a weighted manner the diseases appearing in clause (d) in claim 4.

6. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to claim 5, wherein the weighting of each disease which appears in the cumulative table is a weight correlated with the accumulation of weights with which the said disease appears.

7. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to claim 6, wherein a disease is definitively eliminated if the weight appearing in the cumulative weighting table is exceeded by a predetermined threshold.

8. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to any of the preceding claims, wherein the expert system has means of ensuring that the installation acts indiscriminately under the isolated or combined action of the following input data:

a) knowledge base,

b) user board block,

c) block of external communications with the non-invasive sensors.

9. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to any of the preceding claims wherein the modular system consists of an input/output block which comprises:

a) a screen,

b) a keyboard, both connected to the bus of the installation by one controller for each.

10. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to any of the

preceding claims, wherein the bus includes the main CPU board, a memory extension board containing the dynamic memory block and a controller board connecting the mass memory to the bus.

11. Installation for assisting the diagnosis of cardio-vascular and pulmonary pathologies, according to any of the preceding claims, wherein the main CPU board consists of a CPU and various auxiliary circuits for connection to:

a) an interface for series communications,

b) a ROM memory,

c) a static RAM memory,

d) a clock.

12. Installation for assisting the diagnosis of cardio-vascular and pulmonary pathologies, according to claim 11, wherein the controller board is provided with an auxiliary CPU and its own memory facilities.

13. Installation for assisting the diagnosis of cardio-vascular and pulmonary pathologies, according to any of the preceding claims, wherein the user block consists of:

a) a board containing the data peculiar to the user, which sends its data to:

b) a board reader, which communicates its information to the bus by means of

c) a controller.

14. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, according to any of the preceding claims, further comprising means of asking the installation to supply the situation of the cumulative tables at a given moment, the probable diagnosis being the state of the weighted cumulative table.

15. Installation for assisting the diagnosis of cardiovascular and pulmonary pathologies, substantially as herebefore described with reference to the accomapnying drawings.

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